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10/529,131	11/07/2005	John P. Maye	61843USN(51035)	2561
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EXAMINER				
FLOOD, MICHELE C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,131

Applicant(s)

MAYE, JOHN P.

Examiner

Michele Flood

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on January 28, 2008 with the cancellation of Claims 6-10.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 11-14 are under examination.

Response to Arguments

Claim Objections

Claim 1 is objected to because of the following informalities: There are apparent misspellings in Claim 1. Applicant may overcome the objection by replacing "*Ruminococcus*" with *Ruminococcus*. Appropriate correction is required.

Applicant should also replace "*streptococci*" with *streptococci*; *Lactobacilli* with *lactobacilli*; "Entodini" with *Entodini*; and, "Isotricha" with *Isotricha* to place the claim in proper grammatical form.

The above objection newly applied as necessitated by amendment.

Claim Rejections - 35 USC § 112

Claims 1-5, 11 and 12, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 1 are rendered uncertain by the phrase, "wherein the hop acids are mixed with the feed in an amount to inhibit undesirable bacteria including *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibriosolvens*, *Methanobacterium ruminatum*, various streptococci, *Lactobacilli* and protozoa including *Entodini* and *Isotricha*" because it is unclear as to whether the limitation requires that each of the claim-designated microorganisms are inhibited or whether the limitation requires that some or several of the claim-designated microorganisms are inhibited by the instantly claimed method. The lack of clarity renders the claim vague and ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 5 and 11-14, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Papadopoulou et al. (U). New applied to Claims 4 and 11 as necessitated by amendment.

Applicant claims a method of preparing an organic food supplement using *Humulus lupulus* (hop) acids for livestock comprising mixing the hop acids for oral ingestion with a livestock feed wherein the hop acids are mixed with the feed in an amount to inhibit undesirable bacteria including *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibriosolvens*, *Methanobacterium ruminatum*, various streptococci,

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Lactobacilli and protozoa including *Entodini* and *Isotricha* commonly found in digestive systems of livestock. Applicant further claims the method of claim 1 wherein the hop acids as well as their corresponding salts are selected from at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids. Applicant further claims the method of claim 2 wherein the beta acids are selected from at least one of the group consisting of lupulone, colupulone, and adlupulone. Applicant further claims the method of claim 1 wherein the hop acid is mixed with the feed results in an amount of 2 parts per million (ppm) of hop acid present in fluid of the digestive system of livestock. Applicant further claims the method of claim 1 wherein the livestock is selected from the group consisting of cattle, poultry, horses, pigs, and zoo animals. Applicant further claims the method of claim 1 wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system.

Applicant claims an animal feed comprising a feed plant selected from at least one of the group consisting of corn, barley, alfalfa, wheat, and sorghum, and an effective amount of *Humulus lupulus* (hop) acid capable of inhibiting certain types of undesirable bacteria commonly found in the digestive systems of livestock. Applicant further claims the animal feed of claim 13 wherein the effective amount of hop acid mixed with the feed results in from about 1 parts per million (ppm) to about 30 ppm of hop acid in fluid of digestive systems of the livestock.

Papadopoulou teaches a composition comprising barley and hop beta-acid, wherein the hop-beta acid used was at the levels of 1 ppm and 10 ppm of barley. See

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page 184, Column 2, first line of second paragraph. Papadopoulou further teaches a composition comprising 10 ppm of hop beta acid and barley composition was effective in eliminating the growth of *Escherichia coli*, yeast and fungi, which are undesirable bacteria commonly found in digestive systems of livestock. On page 184, Column 1, second paragraph in its entirety, bridging Column 2, Papadopoulou teaches, "It is well recognized that hop compounds possess antimicrobial properties and these are now being used as preservatives [citations omitted]. The addition of 1 ppm of α -acid during steeping, or at cast, eliminated *Chromobacterium*, *Clavibacterium* and fungi." Given that Papadopoulou teaches mixing barley with hop beta acids (which inherently would include at least lupulone since lupulone is also referred in the art as beta hop acids) in an amount of 10 ppm, the claim-designated functional effect of "2 parts per million (ppm) of hop acid present in fluid of the digestive system fluid of livestock", and the claim-designated functional effect of "wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system" are deemed inherent to the method of making of the organic food supplement taught by Papadopoulou. Given that Papadopoulou teaches mixing barley with hop beta acids (which inherently would include at least lupulone since lupulone is also referred in the art as beta hop acids) in an amount of 10 ppm, the claim-designated limitation of an animal feed "wherein the effective amount of hop acid mixed with the feed results in from about 1 parts per million (ppm) to about 30 ppm of hop acid in fluid of the digestive system of the livestock" is deemed inherent to the composition taught by Papadopoulou.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Papadopoulou to preclude the use of the reference composition as an organic food supplement for livestock.

Given the foregoing, contrary to Applicant's arguments, Papadopoulou clearly teaches the instantly claimed method of preparing an organic supplement for livestock comprising mixing an effective amount of hop acids with a feed plant, namely barley; and, an animal feed thereof.

The reference anticipates the claimed subject matter.

Claims 1, 2, 5 and 11-14, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Arnould et al. (V or W; Translation of foreign non-patent literature provided herein.). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Arnould teaches a method of making an organic food supplement for livestock comprising mixing an effective amount of isohumulone and feed plant, such as Lucerne (also known in the art as alfalfa) and barley. Arnould teaches mixing feed plant, such as

alfalfa and barley, with hop acids comprising including hop alpha acids, wherein the amount of the alpha acids was 61 mg of isohumulones per kg of fresh feed plant. See page 11, under "3.1 *Chemical composition of the malt and hop dregs*", wherein the amount of hop acid mixed with the feed results from about 1 parts per million to about 30 ppm of hop acid. Given that Arnould teaches mixing either alfalfa or barley with hop alpha acids (such as isohumulones) in an amount of 61 mg per 1 kg of fresh feed plant the claim-designated functional effect of "2 parts per million (ppm) of hop acid present in fluid of the digestive system fluid of livestock", and the claim-designated functional effect of "wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system" are deemed inherent to the method of making of the organic food supplement taught by Arnould. Given that Arnould teaches mixing either alfalfa or barley with hop alpha acids (such as isohumulones) in an amount of 61 mg per 1 kg of fresh feed plant, the claim-designated limitation of an animal feed for cattle "wherein the effective amount of hop acid mixed with the feed results in from about 1 parts per million (ppm) to about 30 ppm of hop acid in fluid of the digestive system of the livestock" is deemed inherent to the composition taught by Arnould.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural

difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Arnould to preclude the use of the reference composition as an organic food supplement for livestock.

Given the foregoing, contrary to Applicant's arguments, Arnould clearly teaches the instantly claimed method of preparing an organic supplement for livestock comprising mixing an effective amount of hop acids with a feed plant, namely barley; and, an animal feed thereof.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-5 and 12-14, as amended, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thompson et al. (A*) in view of Schmalreck et al. (V1), Lewis et al. (U1), Chin et al. (W1), Haas et al. (AC, US 6,423,317 B1), Barney et al. (B*), Nutter et al. (D*, US 5,827,895), and Nutter et al. (E*, US 6,313,178 B1) and Johnson et al. (C*), and further in view of Mannering et al. (X), Miller et al. (BG, GB 2072657 A), and Windisch et al. (X1). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 2, 5 and 11-14 was set forth above. Applicant further claims the method of claim 2 wherein the alpha acids are selected from the at least one the group consisting of humulone, cohumulone and adhumulone.

Thompson teaches the instantly claimed inventions. For instance, Thompson teaches a method of preventing the development of liver abscesses in cattle fed on rations containing at least about 75 percent of high energy concentrates selected from the group consisting of corn, grain sorghums, wheat, barley, and molasses having a minimum net energy value of about 1.6 M. Cal./Kg by adding from about 5 percent to about 20 percent dried brewers grains containing spent hops to the ration as an additional source of crude fiber and protein and feeding the ration to the cattle. Thompson teaches that the method of treatment is useful in the prophylaxis of liver abscesses resulting from undesirable bacteria commonly found in the digestive system of livestock, such as streptococci, staphylococci and corynebacteria, and particularly the organism *Spherophorus necrophorus*. Column 1, line 1 to Column 2, line 13. In Table IV, at Column 5-6, Thompson teaches a method of making an organic food supplement for livestock comprising mixing cracked corn (77.55%) and dried brewers grain with yeast (15%) having a net energy value of 1.70 M Cal/Kg; and, an animal feed for livestock thereof.

The claims are drawn to a method of preparing an organic food supplement using *Humulus lupulus* (hop) acids for livestock comprising mixing the hop acids for oral ingestion with a livestock feed wherein the hop acids are mixed with the feed in an amount to inhibit undesirable bacteria including *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibriosolvens*, *Methanobacterium ruminatum*, various streptococci, *Lactobacilli* and protozoa including *Entodini* and *Isotricha* commonly found in digestive systems of livestock. The claims are drawn to an animal feed comprising a feed plant

selected from at least one of the group consisting of corn, barley, alfalfa, wheat, and sorghum, and an effective amount of *Humulus lupulus* (hop) acid capable of inhibiting certain types of undesirable bacteria commonly found in the digestive systems of livestock.

Thompson does not expressly teach that the reference composition comprises hop acids *per se*. However, included also in the mixture used in the animal feed from beer production taught by Thompson is beer yeast, as well as dried brewers grains containing spent hop. However, it is well known in the art of chemistry that both alpha acids and beta alphas are inherent to the brewer's (beer) yeast used in the animal feed taught by Thompson as made evident by the teachings of Mannering (*see* page 312, third paragraph). Additionally, it is well known in the art of chemistry that hop acids are inherent to spent hops as made evident to the teachings of Miller (*see* page 1, Column 1, lines 43-54).

The cited reference discloses a method and an animal feed - - which appear to be identical to the presently claimed inventions since the ingredients used in the making of the reference composition, the method of preparing the product, and the functional effect of the product thereof to inhibit certain types of undesirable bacteria commonly found in the digestive systems of livestock are one the same or essentially the same as instantly claimed by Applicant. Thus, it would appear that the instantly claimed inventions are inherent to the teachings of Thompson, especially given that Mannering teachings that hop acids are inherent to brewers yeast; and, especially given that Miller

teaches that hop acids are inherent to spent hops. Given the foregoing, the reference is considered to anticipate the claimed inventions.

Even if the claimed method and claimed product are not identical to the teachings of Thompson with regard to some unidentified characteristics, the difference between that which is disclosed and that which is claimed are considered to be so slight that the referenced method and reference animal feed are likely to inherently possess the same characteristics of the instantly claimed inventions particularly in view of the similar ingredients and functional effect they have been shown to share. In the alternative, even if the claimed method of using hop acids and claimed product differ from the reference method and reference composition by some unknown factor, such as any of the claim-designated hop acids recited in the Markush group of either Claims 2 or Claim 3, the instantly claimed invention still would have been obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. 103. For instance, it would have been obvious to one ordinary skill in the art to add the claim-designated ingredients to the method of making the composition used in the treatment taught by Thompson and the animal feed thereof to provide the instantly claimed invention because at the time the invention was made it was well known in the art of science that alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids have the claim functional effect to inhibit certain types of undesirable bacteria commonly found in the digestive system of livestock, as evidenced by the teachings of Schmalreck, Lewis and Chin. For instance, both Schmalreck and Lewis teach the antimicrobial activities of lupulones and humulones against undesirable microorganisms

often found as inhabitants of the digestive system of livestock intended for commercial production of food and dairy products for human consumption. For example, in Table 2 on page 209, Schmalreck shows the inhibitory activities of 4-deoxytetrahydro-cohumulone, isocohumulone, isohumulone and humulone against growth of *Bacillus subtilis*, *Micrococcus lysodeikticus*, *Staphylococcus aureus*, *Mycobacterium phlei*, *Streptomyces viridans*, *Saccharomyces cerevisiae* and *Pseudomonas fluorescens*. In Table 1, on page 918, Lewis shows the antibiotic spectra of humulone and lupulone against gram-positive bacteria, acid-fast bacteria, and Actinomycetes. On page 918, lines 3-20, Lewis further teaches that both humulone and lupulone at very low concentrations (about 1 ppm to about 12 ppm) inhibited acid production by a strain of *Lactobacillus bulgaricus*, inhibited the growth of both *Staphylococcus aureus* and *Bacillus mesentericus*, and inhibited the germination of spores of *Bacillus subtilis*. As reported by Lewis in Column 1 of page 916, Chin demonstrates that the oral administration of effective amounts of lupulone inhibits the growth of a virulent strain of *Mycobacterium tuberculosis* without toxicity. At the time the invention was made, it also would have been obvious to add the claim-designated ingredients to the teachings of Thompson to provide the instantly claimed inventions because each of the claim-designated hop acids recited in the Markush groups of Claim 2 and Claim 3 were known in the art for their beneficial functional effect. Firstly, Haas teaches a method of killing protozoa, e.g., ciliates or flagellates, comprising contacting the protozoa with an effective amount of alpha resin (about 100 to about 500 µg/ml) represented by humulone, cohumulone, adhumulone, prehumulone, and posthumulone, and its

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derivatives of isoalpha resin (xanthohumol) and tetra isoalpha resin; and/or an effective amount of beta resin (about 0.1 to about 2.0µg/ml) represented by lupulone, colupulone, adlupulone and prelupulone. Haas demonstrates the anti-protozoal activity of the alpha-acid containing alpha resins and beta-acid containing resins against *Paramecium caudatum*, *Euglena sp.*, *Tetrahymena pyriformis*, *Polytomella papillata*, *Amoeba proteus* and *Chaos sp.* Secondly, Barney teaches a method of inhibiting *Listeria* in a medium comprising administering an effective and save amount of tetrahydroisohumulone (8 ppm to 16 ppm) or hexahydrocolupulone (0.4 ppm to 1.6 ppm) or mixtures or salts thereof. The anti-listerial compounds taught by Barney can be incorporated directly into both liquid and solid foods (meat and poultry) to inhibit the growth of *Listeria* on the surface of foods, or to inhibit the *Listeria* that may be present in or may later enter or come in contact with a medium. Thirdly, Nutter ('895) teaches a method of inhibiting bacterial cell growth of drug resistant *Staphylococcus aureus* or drug resistant *Mycobacterium tuberculosis* in a mammal comprising orally administering an effect amount of hydrogenated lupulones including hexahydrolupulone, hexahydrocolupulone and hexahydroadlupulone. See Column 6, lines 62-67, wherein Nutter teaches the dose amounts of the hop acid compounds required to provide a therapeutic effect. Nutter further teaches that the compounds have been found to have anti-cancer and anti-leishmanial activities. In another instance, Nutter ('178) teaches a therapeutic method for inhibiting the growth of *Mycobacterium avium*-complex in a mammal comprising administering, including the oral route, an effective amount of the immediately mentioned hydrogenated lupulones. Johnson teaches a process of

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applying hop extract or the components of a hop extract containing a mixture of alpha acids, beta acids, and deoxy alpha acids to a food product to inhibit the growth of *Clostridium botulinum* in the food product; and a food product thereof including about 1 ppm or greater of a hop extract or hop extract components (5-100 ppm hop extract; 65% beta resins). Johnson also teaches a food product comprising hop extract wherein the food product delivers about 1 ppm or greater of hop extract or the hop extract components to the stomach or intestine to prevent the growth of *Clostridium difficile*. Moreover, Johnson teaches that the reference method of applying effective amounts of the hop extract or hop acid components to a food product is useful in the inhibition of *Helicobacter pylori* in the stomach or intestine. Finally, Windisch teaches that hop extract comprising hop alpha-acid (humulone) had antibacterial effect against *Butyrivibrio delbrueckii* and Walker taught that humulones, as well as hop beta acids have bacteriostatic action against lactobacilli. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add, in the event that it was even necessary, any of the claim-designated hop acids to the animal feed and the method of use thereof taught by Thompson to provide the instantly claimed inventions because both Schmalreck and Lewis taught that effective amounts of hop acids exert antibacterial activity against undesirable organisms commonly found in the digestive systems of livestock; furthermore, Lewis taught not only the antibacterial activity of humulone and lupulone but also that they possess a lower order of antibiotic activity against of plant pathogenic fungi, on page 918, Column 2, lines 3-20; Chin taught that oral

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administration of an effective amount of lupulone (1500 mg per kilo) to experimental animal models suppressed the development of tuberculosis and exerted tuberculostatic effect *in vivo*; Haas demonstrated the antiprotozoal effect of alpha acids and beta acids against protozoa that lead to human diseases, and others that are pathogenic in the intestinal tract of mammals; Barney taught that hexahydrocolupulones and tetrahydroisohumulones can be incorporated into solid foods at very low concentrations to inhibit the growth or transfer of *Listeria* in a medium, such as a food product; Nutter ('895) taught that hydrogenated lupulones are useful in the making of therapeutic compositions to inhibit not only bacterial cell growth of drug resistant staphylococci and drug resistant mycobacteria but that they are also useful for making pharmaceuticals to inhibit cancer cell growth and bacterial cell growth of *Leishmania tarentolae*; Nutter ('178) also taught that the oral administration of effective amounts of hydrogenated lupulones to mammals beneficially inhibits the growth of *Mycobacterium avium* complex in mammals; and, lastly Johnson taught a process of making a food product for oral ingestion by a mammal comprising apply hop acids to the food product wherein the food product delivers about 1 pp or greater of the hop acids in the stomach or the intestine to prevent growth of *Clostridium difficile* and *Helicobacter pylori*; and, moreover, Johnson taught that the hop acid treated food products could be used to prevent the transmission of these known toxicogenic organisms which are well recognized in the art of microbiology as food pathogens inhabiting the digestive system fluid of livestock and implicated as the causative agent of food poisoning in humans, and other intoxications and infections in humans and/or livestock; Windisch taught that hop extract comprising

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hop alpha-acid (humulone) exerts significant antibacterial effect against *Butyrivibrio delbrucki*; and, Thompson suggested that his method of preventing liver abscesses comprising feeding cattle with the reference composition may be due to the presence of dried brewers yeast, spent hops and fiber therein: "The therapeutic effect may be due to better quality fiber content of dried brewers grains as compared with other sources of roughage. As dried brewers grains has a low spent hop content, it also is possible that a residual hop antiseptic action may be inhibiting the growth of the *S. necrophorus* organisms. The combination of the fiber in dried brewers grains and the antiseptic effect of the hops may be preventing rumenitis to prevent the invasion of the portal veins with the *S. necrophorus* organism.

Thus, the instantly claimed invention would have been no more than a matter of optimization to one of ordinary skill in the art to provide a result effect variable given than the prior art taught that the instantly claimed ingredient of hop acids as well as their corresponding salts not expressly taught by Thompson is well known to be useful in the making of antibacterial pharmaceuticals, like a food product or the animal feed comprising corn, sorghum, wheat or barley and dried brewers yeast containing spent hops taught by Thompson, for oral ingestion by mammals for delivery to the intestine or stomach an effective amount of hop acids because at the time the invention was made it was old and well known in the art that hop acids inhibit undesirable bacteria commonly found in the digestive systems of livestock at a concentration of 1 ppm or greater.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicant's inventions differ and, if

so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicant.

Accordingly, the claimed invention, as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Claims 1- 5 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnould et al. (V or W; Translation of foreign non-patent literature provided herein.) in view of Windisch et al. (X1) and Walker et al. (U2). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

The teachings of Arnould are set forth above. Arnould teaches the instantly claimed invention except for wherein the alpha acids are selected from at least one of the group consisting of humulone, cohumulone and adhumulone; and except for beta acids. However, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and would have a reasonable expectation of success to add at least one of the instantly claimed alpha acids and beta acids to the method of making an organic food supplement and composition thereof taught by Arnould to provide the instantly claimed inventions because at the time the invention was made Windisch taught that hop extract comprising hop alpha-acid

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(humulone) had antibacterial effect against *Butyrivibrio delbrueckii* and Walker taught that humulones, as well as hop beta acids have bacteriostatic action against lactobacilli.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed inventions because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him or her.

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may

be referred to the Electronic Business Center (EBC) at
<http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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